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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,610	06/23/2003	Anke Klippel	1201.102	8727

7590 09/07/2005

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,610	KLIPPEL ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a polynucleotide having the recited limitation in either claim 1 or claim 6, and a cell transformed with the same, classified in class 536, subclass 23.4; class 435, subclass 325.

II. Claims 10-11, drawn to a transgenic fly and a method of screening for an inhibitor of PI 3-kinase, classified in class 800, subclasses 3 and 13.

III. Claims 12-13, drawn to a method of reducing cell death due to trauma in a mammalian patient using a viral or non-viral vector comprising the polynucleotide of the present invention, classified in class 514, subclass 44; class 424, subclass 93.2.

IV. Claim 14, drawn to a method of making 3'-phosphorylated inositol phospholipids using a purified p110 or p110* polypeptide with a vesicle including a PI 3-kinase substrate, classified in class 435, subclass 194.

V. Claims 15-16, drawn to a method of making a 3' phosphorylated inositol phopholipid comprising transforming a host cell with the polynucleotide of the present invention, classified in class 435, subclass 69.1.

VI. Claims 17-18, drawn to a 3' phosphorylated inositol phospholipids made by the methods of the present invention, classified in class 514, subclass 102.

VII. Claim 19, drawn to a method of activating an enzyme effector of PI 3-kinase having a pleckstrin homology domain using a polynucleotide of the present invention, classified in class 435, subclass 6.

VIII. Claim 20, drawn to a method of promoting activation in a mammalian patient of an insulin signaling pathway comprising contacting a cell characterized by insulin resistance with a vector comprising a polynucleotide sequence of the present invention, classified in class 514, subclass 44.

IX. Claim 21, drawn to a method of reducing cell death associated with trauma in a mammalian patient, comprising contacting a population of said patient's cells with an effective amount of a pharmaceutical composition comprising a 3'phosphorylated inositol phospholipids, classified in class 514, subclass 102.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II and VI are drawn to different compositions that are structurally, chemically and biochemically distinct one from the others. For example, the isolated polynucleotide of Group I is composed of nucleotides, whereas the transgenic fly of Group II is a distinct living entity and the 3' phosphorylated inositol phospholipids of Group VI are phospholipids.

Inventions III-V and VII-IX are drawn to distinct methods having different starting materials, different method steps and different desired end-results that require different technical considerations for achieving these end-results. For example, the method of Group III is directed to a gene therapy method for reducing cell death due to trauma in a mammalian patient; the method of Group IV is directed to a method of making 3'-phosphorylated inositol phospholipids using a purified p110 or p110* polypepeptide; the method of Groups V is directed to the synthesis of 3'-phosphorylated inositol phospholipids by transforming a host cell with a polynucleotide of the present invention; the method of Group VII is drawn to the activation of an enzyme effector of PI-3 kinase having a pleckstrin homology domain using a polynucleotide of the present invention; the method of Group VIII is directed to promoting activation in a mammalian patient of an insulin signaling pathway in a cell characterized by insulin resistance; and the method of Group IX is drawn to reducing cell death associated with trauma in a mammalian patient with an effective amount of 3' phosphorylated inositol phospholipids.

Invention I and Inventions III, V, VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of Group I can be used in any one of the distinct methods of Groups III, V, VII and VIII. Invention I is not required for the practice of any other methods.

Invention II is not required for the practice of any of the methods of Groups III-V and VII-IX.

Invention VI and Inventions VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of Group VI can be used in the therapy method of Group IX or in a method for activating an enzyme effector of PI 3-kinase having a pleckstrin homology domain of Group VII.

Additionally, Inventions VI and Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case a 3' phosphorylated inositol phospholipid of Group VI can be made by either the methods of Groups IV and V as well as by chemically modification of inositol phospholipids.

Because these inventions are distinct for the reasons given above, and separate search requirements due to the distinctness of each Invention as discussed in details above in both patented and non-patented literature. Therefore, it would be unduly burdensome for the examiner to **search and/or consider the patentability**

(examination) of all the inventions in a single application. Accordingly, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Dave Nguyen, at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

QUANG NGUYEN, PH.D
PATENT EXAMINER